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| 09/440,829 | 11/15/1999 | ALEX CHENCHIK | CLON-015 | 3481 |

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EXAMINER

FORMAN, BETTY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1634

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/440,829

Applicant(s)

CHENCHIK ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 10-23 and 39-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10-23 and 39-54 is/are rejected.
- 7) ☒ Claim(s) 14 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 November 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 5 November 2004 in which claims 1 and 14 were amended, claim 35 was canceled and claims 39-54 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 5 August 2004, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1-3, 8, 10-23 and 39-54 are under prosecution.

Claim Objections

3. Claim 14 is objected to because of the following: In papers filed 29 June 2004, the claim was amended to recite "covalently bound to the surface of said solid support." The

Art Unit: 1634

instant claim does not include this recitation. The claim is examined as presented. However, it is noted that this element was examined in the previous office action.

Claim 47 is objected to because of the following: The phrase "oligonucleotide nucleotide probes" is redundant and appears to be a typographical error.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 39-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39-46 are indefinite in Claim 39 for the recitation "has low non-specific hybridization characteristics" because it is unclear what the phrase modifies. The phrase follows the description of the probes but the phrase uses the singular "has". Therefore, it is unclear whether the phrase is grammatically incorrect or whether the phrase modifies some other singular component of the array.

Claims 47-54 are indefinite in Claim 47 for the recitation "different probe composition" because the recitation lacks proper antecedent basis in the claim. It is suggested that the claim be amended provide proper antecedent basis e.g. delete "different".

Art Unit: 1634

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 8, 10-23 and 39-46 are rejected under 35 U.S.C. 102(e) as anticipated by Church et al (U.S. Patent No. 6,548,021, filed 11 August 1998).

Regarding Claim 1, Church et al disclose an array comprising a pattern of probe spots covalently attached to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least 10/cm² (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of 60 to about 100nt (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

The instant claims are drawn to probe having a length ranging from 65 to 100nt. Church et al teach probes of 60nt. Furthermore, Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the nucleotides of the polynucleotide spacer. Therefore, the probes of Church are encompassed by the claimed range of 65 to about 100nt.

Regarding Claim 2, Church et al disclose the array wherein two or more nucleic acids hybridize to different probes (Abstract and Column 3, lines 8-13). Church et al teach each probe-primer hybrid forms a different recognition site. Examples of recognition site sequences

Art Unit: 1634

are listed at Column 12-13. Because the different recognition sites differ in sequence, probes of the array hybridize to different targets i.e. primers.

Regarding Claim 3, Church et al disclose the array wherein each probe is hybridizes to a different target (Column 3, lines 8-13 and 30-32).

Regarding Claim 8, Church et al disclose the array wherein the probes are cross-linked to the surface (Column 14, lines 44-64).

Regarding Claim 10, Church et al disclose the array wherein the spots do not exceed a density of 1000/cm² (Column 3, lines 31-33).

Regarding Claim 11, Church et al disclose the array wherein the spots do not exceed a density of 400/cm² (Column 3, lines 31-33).

Regarding Claim 12, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-34).

Regarding Claim 14, Church et al disclose an array comprising a pattern of probe spots covalently bound to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least 10/cm² (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of "about" 65nt bound to the surface of the support (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45). The claims are drawn to probes of "about" 65 nt. The claims and specification do not define the meets and bounds of "about". Therefore, given the broadest reasonable interpretation of the claims, in light of the specification, the 60nt probes of Church are encompassed by the claimed probes of "about 65nt".

Regarding Claim 15, Church et al disclose the array comprises ten or more different probe spots which hybridize to different targets (Column 3, lines 30-32).

Regarding Claim 16, Church et al disclose the array wherein each probe is hybridizes to a different target (Column 3, lines 8-13 and 30-32).

Art Unit: 1634

Regarding Claim 17, Church et al disclose the array wherein two or more nucleic acids hybridize to different probes (Abstract and Column 3, lines 8-13). Church et al teach each probe-primer hybrid forms a different recognition site. Examples of recognition site sequences are listed at Column 12-13. Because the different recognition sites differ in sequence, probes of the array hybridize to different targets i.e. primers.

Regarding Claim 18, Church et al disclose the array wherein the probes are about 65nt i.e. 60nt plus spacer (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the additional polynucleotide spacer. Therefore, the probes are encompassed by the claimed range of 65 to about 95nt.

Regarding Claim 19, Church et al disclose the array wherein the spots do not exceed a density of 1000/cm² (Column 3, lines 31-33).

Regarding Claim 20, Church et al disclose the array wherein the spots do not exceed a density of 400/cm² (Column 3, lines 31-33).

Regarding Claim 21, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-34).

Regarding Claim 22, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-33).

Regarding Claim 23, Church et al disclose an array comprising a pattern of probe spots at a density of at least 10/cm² and does not exceed a density of 400/cm² (Column 3, lines 31-33) wherein and each spot comprises an oligonucleotide probe composition made up of long probes having a length of about 65 to 90nt covalently bound to the surface of the support (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

Art Unit: 1634

Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the nucleotides of the polynucleotide spacer. Furthermore, the claims are drawn to probes of "about" 65 nt. The claims and specification do not define the meets and bounds of "about". Therefore, given the broadest reasonable interpretation of the claims, in light of the specification, the 60nt probes of Church are encompassed by the claimed probes of "about 65nt".

Regarding Claim 39, Church et al disclose an array comprising a pattern of probe spots covalently attached to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least 10/cm² (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of 60 to about 100nt (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

The claim recites "has low non-specific hybridization characteristics". As stated above, it is unclear what the phrase modifies. Furthermore the recitation describes a relative functionality resulting during its use but does not define or describe a structural property or element of the array or probes. Therefore, the recitation is not deemed to define the array over that of Church.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claim 40, Church et al disclose the array comprises two or more different probe spots which hybridize to different targets (Column 3, lines 30-32).

Regarding Claim 41, Church et al disclose the array wherein each probe is hybridizes to a different target (Column 3, lines 8-13 and 30-32).

Art Unit: 1634

Regarding Claim 42, Church et al disclose the array wherein the probes are covalently bound (Column 14, lines 42-45). The instant claim recites "cross-linked to the surface". While the specification (e.g. Example 3) describes a preferred embodiment of cross-linked probes (i.e. UV cross-linked), neither the claim nor specification define the term "cross-linked". Hence, the covalently linkage of Church is deemed to encompass the newly claimed cross-linked.

Regarding Claim 43, Church et al disclose the array wherein the spots do not exceed a density of 1000/cm² (Column 3, lines 31-33).

Regarding Claim 44, Church et al disclose the array wherein the spots do not exceed a density of 400/cm² (Column 3, lines 31-33).

Regarding Claim 45, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-34).

Regarding Claim 46, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-33).

Response to Arguments

8. Applicant asserts that the claims, as amended are drawn to ranges of probe length not disclosed by Church because Church teaches the "overall length does not exceed 60nt". The argument has been considered but is not found persuasive. It is acknowledged that Church teaches probes of 60nt. However, nowhere does Church teach the overall length does not exceed 60nt as asserted. As discussed above and in the previous office action, Church teaches probes comprising 60nt (Column 8, lines 31-35) but Church further teaches the probes have attached thereto spacer regions comprising polynucleotides (Column 13, line 65-Column 14, line 45). Hence, in contrast to Applicant's assertion, Church does not teach an "overall length" not exceeding 60nt. Additionally, independent Claims 14 and 23 are drawn to probes lengths of "about 65" nt. The specification and claims do not define or limit the meets and

Art Unit: 1634

bounds encompassed by "about". Therefore, given the broadest reasonable interpretation of the claims in view of the specification the "about 65" is encompassed by the 60nt specifically taught by Church.

Conclusion

9. Claims 47-54 are free of the prior art and may be placed in condition for allowance following resolution of the above rejections.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Art Unit: 1634

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BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
January 11, 2005